

510(K) Summary

January 07, 2002

JAN 10 2002

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1. **Submitter:** Churchill Medical Systems, Inc.
 Address: 87 Venture Drive
 Dover, NH 03820
 Phone: 603-743-5988
 Fax: 603-743-6328
 Contact: Keith Paluch (Consultant)
2. **Device Name:** Mini Transfer Device
 Trade Name: Vented Vial Access Device
 Classification
 Name: IV Administration Set, Accessory
3. **Classification:** Class II, General Hospital 80 FPA
4. **Predicate Device:** Baxter Healthcare Chemo-Aide Dispensing Pin (K003730)
5. **Device Description:** The Churchill Medical Systems Mini Transfer Device is a standard vented access device. It contains a universal piercing spike with female luer lock and .22 micron hydrophobic filter. The purpose of the filter within the spike body is to provide air-venting.
6. **Intended Use:** This device is used for transferring and or dispensing medications, diluents and additives from rubber stoppered multi dose vials.
7. **Performance Summary:** This device is manufactured and tested in accordance with physical, chemical and biological specification conforming to the applicable requirements set forth in ISO 10993-1, USP 24, ISO 11607-1, ISO 11135, USP Pyrogenicity test requirements as well as documented internal requirements for physical testing.
8. **Conclusion:** This device shares similar technical characteristics to dispensing and transfer devices currently available in the marketplace. Specifically, this device performs similarly to the predicate device, referred to as Chemo-Aide Dispensing Pin Accessory (K003730). Testing summary results confirm this device to be safe and effective and substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2002

Mr. Keith Paluch
Consultant
Churchill Medical Systems, Incorporated
87 Venture Drive
Dover, New Hampshire 03820

Re: K013950
Trade/Device Name: Vented Vial Access Device
Regulation Number: 880.5440
Regulation Name: IV Administration Set, Accessory
Regulatory Class: II
Product Code: LHI
Dated: November 14, 2001
Received: November 30, 2001

Dear Mr. Paluch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

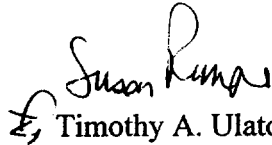
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Susan Rump", is written over the printed name of Timothy A. Ulatowski. The signature is fluid and cursive.

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K013950

Device Name: Churchill Medical Systems Mini Transfer Device

Indications For Use:

Churchill Medical Systems Mini Transfer Device is used for transferring and or dispensing medications, diluents and additives from rubber stoppered multi dose vials.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

Or

Over-The-Counter Use ☐

Sharon Pump
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013950